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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/603,834	06/26/2000	Michael Kraus	39727/DBP/E43	2410

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EXAMINER

OROPEZA, FRANCES P

ART UNIT PAPER NUMBER

3762

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/603,834

Applicant(s)

KRAUS ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 1/26/04 (Amendment).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7 and 9-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-5, 7 and 9-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 22.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Amendment***

1. The rejection of record has been reviewed in light of the amended claims filed by the Applicant on 1/26/04. The rejection of record stands for the reasons discussed at the end of paragraph 2.

***Claim Rejections - 35 USC § 103***

2. Claims 2-4, 7, 9-17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al. (US 5113869) in view of de Coriolis (EPO 0607638).

Nappholz et al. disclose an implantable ambulatory monitor. The telemetry receiver/transmitter performs two-way, digital telemetry to transfer data and programs between the implant and an external device. (col. 16 @ 25-27). The microprocessor of the implant triggers communication with an external device using a beacon signal indicating the reception readiness of the implant, and uses two intervals to control the receiving portion of the implant receiver/transmitter (col. 16 @ 61 – col. 17 @ 6). The reception readiness of the implant is controlled by the synchronization sequence, read as “at least one first item”, sent by the external device (col. 17 @ 13-47). The external receiver/transmitter is substantially permanently ready for data exchange (col. 17 @ 22-25). The implant initiates communications with an external device to provide a warning about abnormal conditions or about implant malfunction (col. 16 @ 34-44). Data communications can be initiated by the implant (col. 21 @ 31-43).

As discussed in the previous paragraph of this action, Nappholz et al. disclose the claimed invention except for:

- the triggering signal including a first data set (claim 4),

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- implementing a first plausibility check (claim 21 and 23),
- implementing renewed transmissions if the power supply is not exceeded (claim 9),
- checking the data (claim 10),
- sending a second acknowledgement (claim 11),
- implementing a second plausibility check (claim 12),
- effecting a new transmission when a defective transmission is established (claim 13),
- effecting renewed transmission after expiry of a waiting time period (claim 14),
- after renewal of the transmission, repeating the method steps (claim 15), and
- upon non-reception of transmissions, prolonging the transmission (claim 17).

De Coriolis discloses a telemetry system for an implantable device including an implant device receiver (44) and transmitter (46) and an external programmer receiver (32) and transmitter (34). The telemetry circuit is used intermittently and contains a wakeup command transaction to enable full activation of the telemetry means (28) (col. 10 @ 49-59). During periods of quiescence, the telemetry means, at spaced apart time intervals, enters a partially active state to detect energy transmissions. If energy is detected, further detection occurs seeking the transmitted initiation command. Once the initiation command is detected, the telemetry system becomes fully active, the receiver sends a response code and the communication transaction begins (col. 11 @ 1-22; col. 20 @ 14-26). The outbound data packet is grouped in fixed length frames, read as intervals, with a preamble (58), a data field (62), a control byte (64), a frame check (containing error code to trigger resending of the data, read as a first acknowledgment) and a postamble (68) used for error detection (col. 12 @ 9-33). The inbound data packet contains a leading flag (74), a data field (78), a control byte (76), a frame check (80)

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(containing error code to trigger resending of the data, read as a second acknowledgment) and a trailing flag (82) (col. 14 @ 2-12). The preamble (58) and the leading flag (74) are read as the triggering signals; this frame contains a first data set and second data set respectively in the data fields. The stay awake signal is read as the waiting time interval (col. 21 @ 37-41). It is inherently understood transmission would not take place in a low battery scenario as therapeutic operations of the implant take priority. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable ambulatory monitor as taught by Nappholz et al., with the specifics of the signal modulation and system component interaction to enable signal transmission as taught by de Coriolis so a known and proven means of signal modulation and system component interaction is adopted to enable data transfer between the implanted device and the remote external unit so the patient's condition can be evaluated and the patient's care optimized.

The Applicant's arguments filed on 1/26/04 have been fully considered, but they are not convincing.

The Applicant asserts Nappholz et al. do not teach implementing a first plausibility check. The Examiner agrees. As noted in the rejection of record, de Coriolis et al. teach implementing a first plausibility check: During periods of quiescence, the telemetry means, at spaced apart time intervals, enters a partially active state to detect energy transmissions. If energy is detected, further detection occurs seeking the transmitted initiation command. Once the initiation command is detected, the telemetry system becomes fully active, the receiver sends a response code and the communication transaction begins (col. 11 @ 1-22; col. 20 @ 14-26). The outbound data packet is grouped in fixed length frames, read as intervals, with a preamble

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(58), a data field (62), a control byte (64), a frame check (containing error code to trigger resending of the data, read as a first acknowledgment) and a postamble (68) used for error detection (col. 12 @ 9-33). The inbound data packet contains a leading flag (74), a data field (78), a control byte (76), a frame check (80) (containing error code to trigger resending of the data, read as a second acknowledgment) and a trailing flag (82) (col. 14 @ 2-12). The preamble (58) and the leading flag (74) are read as the triggering signals; this frame contains a first data set and second data set respectively in the data fields.

The Applicant asserts de Coriolis et al. do not teach the data transmission between the implant and the external device being initiated by the implant. The Examiner agrees. As note in the rejection of record, Nappholz et al. teach the data transmission between the implant and the external device is initiated by the implant: The microprocessor of the implant triggers communication with an external device using a beacon signal indicating the reception readiness of the implant, and uses two intervals to control the receiving portion of the implant receiver/transmitter (col. 16 @ 61 – col. 17 @ 6).

The Applicant asserts since de Coriolis et al. do not teach signal transmission being initiated from the implant to an external device, there is no motivation to combine the references. This argument is moot since as noted above the initiation of the signal transmission from the implant to the external device is taught by Nappholz et al.

3. Claim 5 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al. (US 5113869) in view of in view of de Coriolis (EPO 0607638) and further in view of Fountain et al. (US 4625730). As discussed in paragraph 2 of this action, modified Nappholz et al. disclose the claimed invention except for the triggering signal being initiated by the wearer.

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Fountain et al. disclose an ECG recording controller and teach that it is known to provide a manual means for initiating a triggering pulse to begin a transmission when the patient perceives an emergency situation (abstract; col. 6 starting @ 23). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable ambulatory monitor as taught by modified Nappholz et al., with the manually initiated emergency signal as taught by Fountain et al. to provide a system with a means that enables the patient to get help when he perceives help is needed.

4. Claim 18 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al. (US 5113869) in view of in view of de Coriolis (EPO 0607638) and further in view of Wyborny et al. (US 5354319). As discussed in paragraph 2 of this action, modified Nappholz et al. disclose the claimed invention except for the intervals varying in length.

Wyborney et al. disclose a telemetry system and teach that it is known to use variable interval lengths (col. 5 @ 53-58). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable ambulatory monitor as taught by modified Nappholz et al., with the variable interval lengths as taught by Wybroney et al. to compress the frame length so more data can be transmitted in a fixed time.

***Statutory Basis***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Friday 9 a.m. to 5 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

*FPO*  
*5/2/04*

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